SEP 14 2011

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K112465

Submitter

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Official correspondent :

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Date Prepared:

September 13, 2011

Device name and classification:

- **Device Name:** VSM-300 & VSM-300A Vital Signs Monitors
- **Classification Name:** Non-invasive blood pressure system, oximeter, clinical electronic thermometer
- **Product code:** DQA, DXN, FLL
- **Regulatory Class:** Class II

Predicate Device:

M3 & M3A Vital Signs Monitor K102835 Manufacturer: EDAN Instruments

Device Description:

VSM-300 & VSM-300A Vital Signs Monitors are patient monitoring devices providing the patient with a continuous vital physiological monitoring of non-invasive continuous monitoring of SpO2 (oxygen saturation of the blood), NIBP (non-invasive blood pressure) and TEMP (temperature) in a hospital, hospital type facilities environment and intra-hospital moves. The following lists the detailed features of the subject device.

- LCD or LED display
- SpO2, Pulse Rate NIBP and TEMP measurement
- Nellcor or EDAN SpO2 module
- Display numeric and waveform information simultaneously
- Nurse call feature
- Built-in Lithium-ion Battery
- Suitable for adult, pediatric and neonate patients
- Visual and audible alarm

Intended Use:

The Vital Signs Monitor models VSM-300 and VSM-300A (hereinafter called monitor) are intended to be used for non-invasive continuous monitoring of SpO2 (oxygen saturation of the blood), NIBP (non-invasive blood pressure) and TEMP (temperature).

The monitor is intended to be used only under regular supervision of clinical personnel. It is applicable to adult, pediatric, and neonatal usage in hospitals, hospital type facilities and intra-hospital moves.

The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

Effectiveness and Safety Contraindications:

Non-clinical test:

The following quality assurance measures were applied to the development of the Vital Signs Monitor Models VSM-300 & VSM-300A:

- Software testing
- Safety testing
- Performance testing
- Risk analysis
- Final validation

Comparison to the predicate device:

The subject device has similar technology characteristics and has the same intended use as the predicate device. The VSM-300 & VSM-300A Vital Signs Monitor has the same characteristics as the predicate device cleared under K102835. Both models use the same technology and circuitry.

Substantially Equivalent Determination:

Verification and validation testing was done on the VSM-300 & VSM-300A Vital Signs Monitor. This premarket notification submission demonstrates that VSM-300 & VSM-300A Vital Signs Monitor is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Advanced Instrumentations, Inc.
c/o Jorge Millan, Ph.D.
Executive Director
601 West 20 St
Hialeah, FL 33010

SEP 14 2011

Re: K112465
Trade/Device Name: VSM-300 & VSM-300A Vital Signs Monitors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II (two)
Product Code: DQA, DXN, FLL
Dated: August 23, 2011
Received: August 26, 2011

Dear Dr. Millan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112465 1/1

Indications for Use

510(k) Number (if known):

Device Name:

VSM-300 & VSM-300A Vital Signs Monitor

Indications for Use:
The Vital Signs Monitors models VSM-300 and VSM-300A (hereinafter called monitor) are intended to be used for non-invasive continuous monitoring of SpO2 (oxygen saturation of the blood), NIBP (non-invasive blood pressure) and TEMP (temperature).

The monitors are intended to be used only under regular supervision of clinical personnel. It is applicable to adult, pediatric, and neonatal usage in hospitals, hospital type facilities and intra-hospital moves.

The monitors are equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

Prescription Use _X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112465